IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF MARYLAND

SAN SAN YU, *Plaintiff*, v. KONINKLIJKE PHILIPS N.V.; PHILIPS NORTH AMERICA LLC; and PHILIPS RS NORTH AMERICA LLC, *Defendants*.	Civil Action No.: COMPLAINT AND DEMAND FOR JURY TRIAL

Plaintiff San San Yu, by and through her undersigned counsel, hereby brings this Complaint and Demand for Jury Trial against Defendants KONINKLIJKE PHILIPES N.V. ("Philips NV"), PHILIPS NORTH AMERICA LLC ("Philips NA"), PHILIPS HOLDING USA, INC. ("Philips Holding"), and PHILIPS RS NORTH AMERICA LLC ("Philips RS"), and alleges the following upon information and belief.

INTRODUCTION

1. Plaintiff San San Yu developed lung cancer and thyroid cancer as a result of using her Philips DreamStation Auto CPAP device. Plaintiff has already undergone two surgeries and will definitely need further treatment.

2. On September 29, 2021, Plaintiff San San Yu received a letter and Recall Notice from Philips regarding her DreamStation CPAP device. The letter stated in part, "Philips Respironics recently announced a voluntary recall for certain products in our Sleep & Respiratory Care portfolio. You are receiving this letter because you, or the medical equipment company that you work with, has provided your information and indicated you may be the user of a product impacted by this recall."[1]

3. Philips researches, develops, designs, manufactures, sells, distributes, and markets a variety of Bilevel Positive Airway Pressure ("BiPAP") and Continuous Positive Airway Pressure ("CPAP") devices, which are used to treat obstructive sleep apnea ("OSA"), and a variety of mechanical ventilators ("ventilators"), which are used to treat respiratory failure.

4. On June 14, 2021, Philips announced a major recall of millions of BiPAP and CPAP devices and ventilators (collectively, "the recalled devices") and first notified the public of potential, serious health risks caused by polyester-based polyurethane sound abatement foam ("PE-PUR foam") used in the design and manufacture of the recalled devices.

5. Philips notified the public that the PE-PUR foam could degrade, break down, and release toxic particulates and volatile organic compounds ("VOCs") into the air pathway of the recalled devices, which a device user could inhale or ingest and suffer toxic or carcinogenic effects.

6. On July 22, 2021, the United States Food and Drug Administration ("FDA") classified the subject recall as Class I, the most serious type of recall, which indicates that use of the recalled devices may cause serious injuries or death.

7. Philips knew or should have known about these potentially life-threatening health risks prior to the recall, but did nothing to warn patients or their physicians.

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[1] *See* Philips Recall Notice attached hereto as Exhibit "A."

8. Plaintiff San San Yu was prescribed, purchased, and used on a daily basis, for numerous years, a Philips DreamStation Auto CPAP [Serial No. J20078394C7DE] (hereinafter, "the subject device").

9. As a direct and proximate result of Philips's wrongful conduct in researching, developing, designing, manufacturing, selling, distributing, and marketing the subject device, and in failing to warn consumers and the medical community regarding the device's latent and foreseeable risks, Plaintiff developed thyroid cancer and lung cancer in both her right and left lungs, all of which are severe and life-altering injuries.

PARTIES

8. Plaintiff San San Yu is a United States citizen and resident of Baltimore, Maryland.

9. Plaintiff was prescribed the subject device for the treatment of OSA by Dr. Ahmed of Saint Agnes Hospital in Baltimore, Maryland.

10. Plaintiff purchased the subject device in Maryland from a medical equipment company called Bay State Medical, Inc. An employee of Bay State Medical, Inc. personally delivered the subject device to Plaintiff's house.

11. Plaintiff's use of the subject device occurred on a daily basis in Maryland.

12. At all relevant times, Plaintiff used the subject devices for the purpose for which they were researched, developed, designed, manufactured, sold, distributed, marketed and otherwise intended for.

13. As a result of using the subject device, Plaintiff was exposed to toxic and harmful substances and suffered severe personal injuries that would not have occurred but for the defective nature of the subject device and Philips's failure to warn Plaintiff or her physicians of the serious health risks associated with use of the subject device.

14. Defendant Royal Philips is a Dutch multinational corporation with its principal place of business located in Amsterdam, Netherlands. Royal Philips is the parent company of the Philips Group of healthcare technology businesses, including Connected Care businesses focusing on Sleep & Respiratory Care. Royal Philips holds directly or indirectly 100% of its subsidiaries Philips NA and Philips RS. Upon information and belief, Royal Philips controls Philips NA and Philips RS in the manufacturing, selling, distributing, and supplying of the recalled CPAP, Bi-Level PAP, and mechanical ventilator devices.

15. Defendant Philips NA is a Delaware corporation with its principal place of business located at 222 Jacobs Street, Floor 3, Cambridge, Massachusetts 02141. Philips NA is a wholly-owned subsidiary of Royal Philips.

16. Defendant Philips RS is a Delaware corporation with its principal place of business located at 6501 Living Place, Pittsburgh, Pennsylvania 15206. Philips RS is a wholly-owned subsidiary of Royal Philips. Philips RS was formerly operated under the business name Respironics, Inc. ("Respironics"). Royal Philips acquired Respironics in 2008.

JURISDICTION AND VENUE

17. Jurisdiction of this Court is based on Diversity of Citizenship and the amount in controversy is well in excess of the jurisdictional limit of $75,000.00. 28 U.S.C. Section 1332(a)(1).

18. Personal jurisdiction is proper in this Court as Defendants serve a market for the Subject Device in Maryland (including this District), Plaintiff purchased her recalled device in Maryland (within this District), and Plaintiff's losses at issue occurred in Maryland (within this District). Further, Defendants conduct business in Maryland, have sufficient minimum contacts in Maryland, and purposefully and intentionally avail themselves of the markets within Maryland

through the promotion, sale, marketing, and distributions of its products including the Subject Device. The unlawful acts of Defendants that are the subject matter of this case have been directed at, targeted, and have had the effect of causing injury to persons residing in Maryland and in this District, as well as throughout the United States.

19. Venue is proper in this District pursuant to 28 U.S.C. § 1391 because Defendants transact business in this District and a substantial part of the events or omissions giving rise to Plaintiff's claims occurred in this District.

FACTUAL BACKGROUND

I. Continuous Positive Airway Pressure Therapy

20. Continuous Positive Airway Pressure ("CPAP") therapy is a common nonsurgical treatment primarily used to treat sleep apnea. CPAP therapy typically involves the use of a hose and a nasal or facemask device that delivers constant and steady air pressure to an individual's throat to help individuals breathe.

21. Sleep apnea is a common sleep disorder characterized by repeated interruptions in breathing throughout an individual's sleep cycle. These interruptions, called "apneas," are caused when the soft tissue in an individual's airway collapses. The airway collapse prevents oxygen from reaching the individual's lungs which can cause a buildup of carbon dioxide. If the individual's brain senses the buildup of carbon dioxide, it will briefly rouse the individual from sleep so that the individual's airway can reopen. Often these interruptions are so brief that the individual will not remember. Despite the brevity of the interruptions, the sleep cycle disruption caused by sleep apnea can dramatically impact a person's lifestyle, including negatively impacting energy, mental performance, and long-term health. CPAP therapy helps treat sleep

apnea by preventing the person's airway from collapsing while breathing during sleep cycles, which can help prevent interruptions in breathing.

II. Bi-Level Positive Airway Pressure Therapy

22. Bi-Level Positive Airway Pressure ("BiPAP") therapy is a common alternative to CPAP therapy for treating sleep apnea. Similar to CPAP therapy, BiPAP therapy is nonsurgical and involves the use of a nasal or facemask device to maintain air pressure in an individual's airway. BiPAP therapy is distinguishable from CPAP therapy, however, because Bi-Level PAP devices deliver two alternating levels—inspiratory and expiratory—of pressurized air into a person's airway, rather than the single continuous level of pressurized air delivered by a CPAP device. The inspiratory positive airway pressure assists a person as a breath is taken in. Conversely, the expiratory positive airway pressure is applied to allow a person to comfortably breathe out. Bi-Level PAP devices deliver one level of pressurize air (the inspiratory positive level) to assist as a person inhales, and another level (the expiratory level) as a person exhales.

III. Mechanical Ventilation

23. Mechanical ventilation is a treatment to help a person breathe when they find it difficult or are unable to breathe on their own. A mechanical ventilator pushes airflow into the patient's lungs to help them breathe. Mechanical ventilation may be invasive ventilation with a tube inserted into the patient's airway, performed in the intensive care unit in the hospital or a long-term institutional setting. Non-invasive ventilation can be used at home by people with respiratory difficulties.

SUBSTANTIVE ALLEGATIONS

24. Philips developed, marketed, and sold a variety of CPAP and Bi-Level PAP respirator devices and mechanical ventilators under its "Sleep & Respiratory Care" segment of its business

designed to assist individuals with a number of sleep, breathing, and respiratory conditions, including obstructive sleep apnea, central sleep apnea, complex sleep apnea syndrome, and Chronic Obstructive Pulmonary Disease (COPD), as well as to assist those individuals requiring invasive and non-invasive ventilators for acute and sub-acute hospital environments. Philips' CPAP and Bi-Level PAP respirator devices and its mechanical ventilators typically cost several hundred, if not thousands of dollars. Philips has sold millions of these devices in the United States.

IV. Philips Sleep & Respiratory Care Devices Endangered Users

25. On April 26, 2021, in its Quarterly Report for Q1 2021, Philips disclosed for the first time, under a section entitled "Regulatory Update," that device user reports had led to a discovery that the type of PE-PUR Foam Philips used to minimize noise in several CPAP and Bi-Level PAP respirators and mechanical ventilators posed health risks to its users. Specifically, Philips disclosed that "the [PE-PUR] foam may degrade under certain circumstances, influenced by factors including use of unapproved cleaning methods, such as Ozone, and certain environmental conditions involving high humidity and temperature."

26. Seven weeks later, on June 14, 2021, Philips announced a recall of numerous models of CPAP and Bi-Level PAP devices, as well as a variety of its mechanical ventilators "to address identified potential health risks related to the polyester-based polyurethane (PE-PUR) sound abatement foam component in these devices." Specifically, Philip announced that it had determined that the "PE-PUR foam may degrade into particles which may enter the device's air pathway and be ingested or inhaled by the user, and the foam may off-gas certain chemicals." In total, Philips announced that "[b]etween 3 million and 4 million" devices are targeted in the recall.

27. Philips reported to physicians that PE-PUR Foam particles "may cause irritation and airway inflammation, and this may be particularly important for patients with underlying lung diseases or reduced cardiopulmonary reserve."

28. Further, Philips reported that "based on lab testing and evaluations, it may be possible that these potential health risks could result in a wide range of potential patient impact, from transient potential injuries, symptoms and complications, as well as possibly serious injury which can be life-threatening or cause permanent impairment, or require medical intervention to preclude permanent impairment."

29. Philips announced that it has received reports of specific complaints from users of Recalled Devices who suffered from "headache[s], upper airway irritation, cough, chest pressure and sinus infection."

V. The Health Risks Associated with Use of the Recalled Devices Renders Them Worthless

30. As a result of the health risks associated with the use of the Recalled Devices, together with Defendants' concealment of these risks from the date they were first reported to Defendants or discovered by Defendants through April 26, 2021, the Recalled Devices have been rendered completely worthless or, at the very least, have been substantially diminished in value.

31. The information described above, including the now-known health risks of Philips CPAP devices, Bi-Level PAP devices and mechanical ventilators, the recall, and the medical warnings and advice issued by Philips, have rendered the Recalled Devices worthless to patients with sleep apnea and respiratory conditions. Individuals not using life-supporting ventilators must immediately discontinue their use of the Recalled Devices or face serious health risks as grave as organ failure or cancer. If they choose to discontinue use of the Recalled Devices they must pay

for another expensive device in order to receive effective treatment for their sleep apnea and/or respiratory conditions. Individuals using life-supporting ventilators must seek an alternative treatment before discontinuing use of the Recalled Device.

VI. Philips Unreasonably Delayed its Recall

32. At no time prior to its Regulatory Update on April 26, 2021, did Philips disclose to purchasers or users of the Recalled Devices that the PE-PUR Foam contained therein may off-gas or degrade upon use. Similarly, prior to the Update, Philips did not disclose any health risks associated with use of the Recalled Devices.

33. Defendants have not disclosed when they first discovered or received reports from users of their Sleep & Respiratory Care devices "regarding the presence of black debris/particles within the airpath circuit (extending from the device outlet, humidifier, tubing, and mask)."

34. At a minimum, as a result of user reports, Defendants were aware of the off-gassing and degradation of the PE-PUR Foam used in the Recalled Devices at some point prior to the recall, yet continued to manufacture and sell the Recalled Devices with such awareness. During this period, Defendants unreasonably and unjustly profited from the manufacture and sale of the Recalled Devices and unreasonably put users of the Recalled Devices at risk of development of serious adverse health effects, including organ failure and cancer.

VII. Plaintiff San San Yu

35. Plaintiff San San Yu is a resident of Baltimore, Maryland.

36. Plaintiff San San Yu purchased a Recalled Device, a Philips DreamStation CPAP device, sometime in 2018.

37. The manuals accompanying Plaintiff San San Yu's Philips DreamStation CPAP device did not contain any language or warnings of health risks associated with use of the device,

including irritation (skin, eye, and respiratory tract), inflammatory response, headache, asthma, adverse effects to other organs (e.g., kidneys and liver) and toxic carcinogenic effects. Had Defendants informed Plaintiff of these risks, she would not have purchased or used the Recalled Device.

38. Without knowing of the health risks associated with use of the Recalled Device, Plaintiff San San Yu used her Recalled Device every day for approximately ten to eleven hours each day to treat sleep apnea.

39. As a result of the health risks associated with continued use of the Philips DreamStation CPAP device, Plaintiff San San Yu was diagnosed with lung cancer and thyroid cancer. Plaintiff San San Yu underwent surgery for her lung cancer on April 5, 2021, and then another surgery for her thyroid cancer on June 30, 2021.

TOLLING AND ESTOPPEL

I. DISCOVERY RULE TOLLING

40. Plaintiff had no way of knowing about Philips' conduct with respect to the health risks associated with the use of the Recalled Device.

41. Plaintiff, through the exercise of reasonable care, could not have discovered the conduct by Philips alleged herein. Further, Plaintiff did not discover and did not know of facts that would have caused a reasonable person to suspect that Philips was engaged in the conduct alleged herein.

42. For these, reasons, all applicable statutes of limitation have been tolled by the discovery rule with respect to claims asserted by Plaintiff.

II. **FRAUDULENT CONCEALMENT TOLLING**

43. By failing to provide immediate notice of the adverse health effects associated with continued use of the Recalled Device, Philips concealed its conduct and the existence of the claims asserted herein from Plaintiff.

44. Upon information and belief, Philips intended its acts to conceal the facts and claims from Plaintiff. Plaintiff was unaware of the facts alleged herein without any fault or lack of diligence on her part and could not have reasonably discovered Defendants' conduct. For this reason, any statute of limitations that otherwise may apply to the claims of Plaintiff should be tolled.

CLAIMS FOR RELIEF

FIRST CAUSE OF ACTION
NEGLIGENCE

45. Defendants had a duty to individuals, including the Plaintiff, to use reasonable care in designing, manufacturing, marketing, labeling, packaging and selling the recalled machines, including the Philips DreamStation CPAP device.

46. Defendants were negligent in failing to use reasonable care as described herein in designing and manufacturing, the recalled machines, as well as the Philips DreamStation CPAP device that Plaintiff purchased and used. Defendants breached their aforementioned duty by:

a. Failing to design the recalled machines, as well as the Philips DreamStation CPAP device so as to avoid an unreasonable and increased risk of harm of lung damage, lung cancer, thyroid damage, thyroid cancer, and other injuries in users;

b. Including in the design of the recalled machines, as well as the Philips DreamStation CPAP device, flawed polyurethane PE-PUR sound abatement foam that

could break down, flake off and/or chemicalize and infiltrate the device's air pathway while the user is sleeping, exposing them to increased and unnecessary risk of cancer, including lung cancer and thyroid cancer, as well as other injuries;

c. Manufacturing certain Philips machines, including the recalled machines and the Philips DreamStation CPAP device with a specific lot and/or lots of flawed polyurethane PE-PUR sound abatement foam that could break down, flake off and/or chemicalize and infiltrate the device's air pathway while the user is sleeping, exposing them to increased and unnecessary risk of cancer, including lung cancer and thyroid cancer, as well as other injuries;

d. Otherwise negligently or carelessly designing, manufacturing, marketing, labeling, packaging and/or selling the Philips DreamStation CPAP device.

47. Defendant also negligently failed to warn or instruct the Plaintiff in the following manners:

a. the recalled machines, including the Philips DreamStation CPAP device's flawed polyurethane PE-PUR sound abatement foam propensities to break down, flake off and/or chemicalize and infiltrate the device's air pathway while the user is sleeping, exposing them to increased and unnecessary risk of cancer, including lung cancer and thyroid cancer, as well as other injuries;

b. the recalled machines, including the Philips DreamStation CPAP device's polyurethane PE-PUR sound abatement foam propensities to degradation, fragmentation and/or chemicalization;

c. the rate and manner in which the polyurethane PE-PUR sound abatement foam would break down, flake off and/or chemicalize and infiltrate the device's air pathway while the user is sleeping;

d. The risk of chronic inflammation resulting from use of the recalled machines, including the Philips DreamStation CPAP device;

e. the risk of chronic infections resulting from the recalled machines, including the Philips DreamStation CPAP device;

f. the risk of lung cancer, thyroid cancer, and other cancers from exposure to the foam;

g. the need for corrective or revision surgery to adjust or remove cancerous tumors and/or nodules as a result of usage of the recalled machines, including the Philips DreamStation CPAP device;

h. the severity of complications that could arise as a result of implantation of the recalled machines, including the Philips DreamStation CPAP device;

48. As a direct and proximate result of Defendants' negligence, the Plaintiff has experienced significant mental and physical pain and suffering, has sustained permanent injury, has undergone medical treatment and will definitely undergo further medical treatment and procedures, has suffered financial or economic loss, including, but not limited to, obligations for medical services and expenses, lost income, and other damages.

WHEREFORE, Plaintiff demands judgment against Defendants, and each of them, individually, jointly, severally and in the alternative, and requests compensatory damages, punitive damages, together with interest, costs of suit, attorneys' fees, and such further relief as the Court deems equitable and just.

SECOND CAUSE OF ACTION
DESIGN DEFECT

49. The recalled machines, including the Philips DreamStation CPAP device machine used by Plaintiff was not reasonably safe for its intended uses and was defective as described herein with respect to its design. As previously stated, the Philips DreamStation CPAP device machine's design defects include, but are not limited to:

a. the use of polyurethane PE-PUR sound abatement foam in the recalled machines, including the Philips DreamStation CPAP device machine and the immune reaction that results from such material, causing adverse reactions and injuries;

b. Failing to design the recalled machines, as well as the Philips DreamStation CPAP device machine so as to avoid an unreasonable and increased risk of harm of cancer and other injuries in users;

c. Including in the design of the recalled machines, as well as the Philips DreamStation CPAP device, flawed polyurethane PE-PUR sound abatement foam that could break down, flake off and/or chemicalize and infiltrate the device's air pathway while the user is sleeping, exposing them to increased and unnecessary risk of cancer, including lung cancer and thyroid cancer, as well as other injuries;

d. Failing to use alternatively available sound abatement materials and/or foams in the recalled machines, as well as the Philips DreamStation CPAP device machine, such as plastic, silicone, or rubber, which would not break down, flake off and/or chemicalize and infiltrate the device's air pathway while the user is sleeping;

e. Otherwise negligently or carelessly designing, manufacturing, marketing, labeling, packaging and/or selling the recalled machines, including the Philips DreamStation CPAP device.

50. At all times, the use of the recalled machines, as well as Plaintiff's use of the Philips DreamStation CPAP device (and its components, such as the facemask) was at all times foreseeable and foreseen by Defendants as it was used by Plaintiff in the manner intended by Defendants.

51. The recalled machines, including the Philips DreamStation CPAP device machine used by Plaintiff, was defective in their design in that they failed to perform as safely as a reasonable consumer would expect when used in an intended or reasonably foreseeable manner.

52. The recalled machines, including the Philips DreamStation CPAP device used by Plaintiff are further defective in that the risks of danger inherent in its design outweigh the benefits, in that the gravity of danger posed by the design was great, the likelihood that such danger would cause injury was substantial, there were feasible, safer alternative designs known to Defendants at the time of manufacture, the financial costs of an improved design was minor and there were likely no adverse consequences to the product, or to the user, that would result from an alternative design.

53. Defendants, and each of them, knew that the recalled machines, including the Plaintiff's DreamStation machine, and the component parts of these CPAP machines would be purchased and used without inspection for defects in the design of the machine or its masks/attachments.

54. The recalled machines, including the Plaintiff's DreamStation machine, and the component parts of these CPAP machines were defective when they left the control of each of these Defendants.

55. As a direct and proximate result of the recalled machines, including Plaintiff's defective Philips DreamStation CPAP device and its aforementioned defects as described herein, the Plaintiff has experienced significant mental and physical pain and suffering, has sustained

permanent injury, has undergone medical treatment and will definitely undergo future medical treatment and procedures, has suffered financial or economic loss, including, but not limited to, obligations for medical services and expenses, lost income, and other damages.

56. Defendants are strictly liable to the Plaintiff for designing, manufacturing, marketing, labeling, packaging and selling the recalled machines, including Plaintiff's defective Philips DreamStation CPAP device(s).

57. As a direct and proximate result of one or more of the above-stated negligent acts, Plaintiff has suffered and will continue to suffer injury of a personal and pecuniary nature, including pain and suffering, medical expenses, lost income, and disability.

WHEREFORE, Plaintiff demands judgment against Defendants, and each of them, individually, jointly, severally and in the alternative, and requests compensatory damages, punitive damages, together with interest, costs of suit, attorneys' fees, and such further relief as the Court deems equitable and just.

THIRD CAUSE OF ACTION
MANUFACTURING DEFECT

58. At all times, the use of the recalled machines, as well as Plaintiff's use of the Philips DreamStation CPAP device (and its components, such as the facemask) was at all times foreseeable and foreseen by Defendants as it was used by Plaintiff in the manner intended by Defendants.

59. The recalled machines, including the Philips DreamStation CPAP device used by Plaintiff were defective at the time of their manufacture, development, production, testing, inspection, endorsement, sale and distribution, and at the time they left the possession of the Defendants, in that, and not by way of limitation, the products differed from the Defendants'

intended result and intended design and specifications, and from other ostensibly identical units of the same product line.

60. Defendants, and each of them, knew or should have known of the defective nature of the recalled machines, including the Philips DreamStation CPAP device used by Plaintiff, including (among other things), that the PE-PUR foam used in the recalled machine's component parts was prone to flaking, chemicalization, disintegration, that it could enter the user's airways while they slept, and created an unreasonably high risk while in use, and would foreseeably result in injury or death to the public, purchasers, and/or consumers.

61. The Defendants, and each of them, knew or should have known of the defective nature of the recalled machines, including the Plaintiff's DreamStation machine, and the component parts of these CPAP machines, including among other things, that the PE-PUR foam used in the recalled machine's component parts was prone to flaking, chemicalization, disintegration, that it could enter the user's airways while they slept, and created an unreasonably high risk while in use, and would foreseeably result in injury or death to the public, purchasers, and/or consumers.

62. Specifically, the Defendants improperly designed the recalled machines, including the Plaintiff's DreamStation machine, by:

a. Manufacturing certain Philips machines, including the recalled machines and the recalled machines, including the Philips DreamStation CPAP device with a specific lot and/or lots of flawed polyurethane PE-PUR sound abatement foam that could break down, flake off and/or chemicalize and infiltrate the device's air pathway while the user is sleeping, exposing them to increased and unnecessary risk of cancer, including lung cancer and thyroid cancer, as well as other injuries;

63. As a direct and proximate result of one or more of the above-stated negligent acts, Plaintiff has suffered and will continue to suffer injury of a personal and pecuniary nature, including pain and suffering, medical expenses, lost income, and disability.

WHEREFORE, Plaintiff demands judgment against Defendants, and each of them, individually, jointly, severally and in the alternative, and requests compensatory damages, punitive damages, together with interest, costs of suit, attorneys' fees, and such further relief as the Court deems equitable and just.

FOURTH CAUSE OF ACTION
FAILURE TO WARN

64. The recalled machines, including the Philips DreamStation CPAP device used by Plaintiff were not reasonably safe for their intended uses and were defective as described herein as a matter of law due to its lack of appropriate and necessary warnings. Specifically, Defendants did not provide sufficient or adequate warnings including, but not limited to, the following:

a. the recalled machines, including the Philips DreamStation CPAP device's flawed polyurethane PE-PUR sound abatement foam propensities to break down, flake off and/or chemicalize and infiltrate the device's air pathway while the user is sleeping, exposing them to increased and unnecessary risk of cancer, including lung cancer and thyroid cancer, as well as other injuries;

b. the recalled machines, including the Philips DreamStation CPAP device's polyurethane PE-PUR sound abatement foam propensities to degradation, fragmentation and/or chemicalization;

c. the rate and manner in which the polyurethane PE-PUR sound abatement foam would break down, flake off and/or chemicalize and infiltrate the device's air pathway while the user is sleeping;

d. The risk of chronic inflammation resulting from use of the recalled machines, including the Philips DreamStation CPAP device;

e. the risk of chronic infections resulting from the recalled machines, including the Philips DreamStation CPAP device;

f. the risk of lung cancer, thyroid cancer, or other cancers from exposure to the foam;

g. the need for corrective or revision surgery to adjust or remove cancerous tumors and/or nodules, such as the lung and thyroid cancer suffered by Plaintiff as a result of usage of the recalled machines, including the Philips DreamStation CPAP device;

h. the severity of complications that could arise as a result of implantation of the recalled machines, including the Philips DreamStation CPAP device;

65. As a direct and proximate result of the recalled machines, including the Philips DreamStation CPAP device's aforementioned defects as described herein, the Plaintiff has experienced significant mental and physical pain and suffering, has sustained permanent injury, has undergone medical treatment and will definitely undergo further medical treatment and procedures, has suffered financial or economic loss, including, but not limited to, obligations for medical services and expenses, and/or lost income, and other damages.

66. Defendants are strictly liable to the Plaintiff for designing, manufacturing, marketing, labeling, packaging and selling a defective Philips DreamStation CPAP device(s).

WHEREFORE, Plaintiff demands judgment against Defendants, and each of them, individually, jointly, severally and in the alternative, and requests compensatory damages, punitive damages, together with interest, costs of suit, attorneys' fees, and such further relief as the Court deems equitable and just.

FIFTH CAUSE OF ACTION
BREACH OF EXPRESS WARRANTY

67. Philips marketed and sold the Recalled Device into the stream of commerce with the intent that the Recalled Device would be purchased by Plaintiff and other members of the general public.

68. Philips expressly warranted, advertised, and represented to Plaintiff that the Recalled Device was safe and appropriate for human use.

69. Philips made these express warranties regarding the Recalled Device's quality and fitness for use in writing through its website, advertisements, and marketing materials, and on the Recalled Device's packaging and labels. These express warranties became part of the basis of the bargain that Plaintiff entered into upon purchasing the Recalled Device.

70. Philips' advertisements, warranties, representations, and omissions regarding health risks associated with the Recalled Device, were made in connection with the sale of the Recalled Device to Plaintiff. Plaintiff relied on Philips' advertisements, warranties, representations, and omissions regarding the Recalled Device in deciding whether to purchase and use Philips' Recalled Device.

71. Philips' recalled machines, including the Philips DreamStation CPAP device used by Plaintiff, do not conform to Philips' advertisements, warranties, representations, and omissions

in that they are not safe, healthy, and appropriate for human use, and pose risks of serious injury and disease, including organ failure and cancer.

72. Philips therefore breached its express warranties by placing the The recalled machines, including the Philips DreamStation CPAP device used by Plaintiff, into the stream of commerce and selling it to consumers, when their use posed health risks, had dangerous effects and were unsafe, rendering these products unfit for their intended use and purpose, and unsafe and unsuitable for consumer use as marketed by Philips. These associated health effects substantially impair the use, value, safety of the Recalled machines, including the Philips DreamStation CPAP device used by Plaintiff, and rendered it worthless.

73. Philips was aware, or should have been aware, of the toxic or dangerous health effects of the use of the Recalled machines, including the Philips DreamStation CPAP device used by Plaintiff, but nowhere on the package labeling or package inserts or on Philips' websites or other marketing materials did Philips warn Plaintiff he was at risk of developing adverse health effects as a result of the dangerous PE-PUR Foam used in the Recalled machines, including the Philips DreamStation CPAP device used by Plaintiff.

74. Instead, Philips concealed the dangerous health effects of the PE-PUR Foam used in the Recalled machines, including the Philips DreamStation CPAP device used by Plaintiff and deceptively represented that these products were safe, healthy, and appropriate for use. Philips thus utterly failed to ensure that the material representations they were making to consumers were true.

75. The adverse health effects associated with use of the Recalled machines, including the Philips DreamStation CPAP device used by Plaintiff existed when they left Philips' possession or control and were sold to Plaintiff. The dangers associated with use of the Recalled machines,

including the Philips DreamStation CPAP device used by Plaintiff were undiscoverable by Plaintiff at the time of purchase of the Recalled machines, including the Philips DreamStation CPAP device used by Plaintiff.

76. As manufacturers, marketers, advertisers, distributors and sellers of the Recalled machines, including the Philips DreamStation CPAP device used by Plaintiff, Philips had exclusive knowledge and notice of the fact that the Recalled machines, including the Philips DreamStation CPAP device used by Plaintiff did not conform to the affirmations of fact and promises.

77. In addition, or in the alternative, to the formation of an express contract, Philips made each of the above-described representations and omissions to induce Plaintiff to rely on such representations and omissions.

78. Philips' affirmations of fact and promises and its omissions were material, and Plaintiff reasonably relied upon such representations and omissions in purchasing and using the Recalled machines, including the Philips DreamStation CPAP device used by Plaintiff.

79. All conditions precedent to Philips' liability for its breach of express warranty have been performed by Plaintiff.

80. Affording Philips an opportunity to cure its breaches of written warranties would be unnecessary and futile here. Philips was placed on reasonable notice from user reports and its lab testing that the PE-PUR Foam in the Recalled machines, including the Philips DreamStation CPAP device used by Plaintiff was unsafe. Philips had ample opportunity either to stop using the PE- PUR Foam or to replace the PE-PUR Foam in the Recalled machines, including the Philips DreamStation CPAP device used by Plaintiff to make them safe and healthy for use by Plaintiff, but failed to do so until now.

81. As a direct and proximate result of the recalled machines, including the Philips DreamStation CPAP device's aforementioned defects as described herein, the Plaintiff has experienced significant mental and physical pain and suffering, has sustained permanent injury, has undergone medical treatment and will definitely undergo further medical treatment and procedures, has suffered financial or economic loss, including, but not limited to, obligations for medical services and expenses, and/or lost income, and other damages.

WHEREFORE, Plaintiff demands judgment against Defendants, and each of them, individually, jointly, severally and in the alternative, and requests compensatory damages, punitive damages, together with interest, costs of suit, attorneys' fees, and such further relief as the Court deems equitable and just.

SIXTH CAUSE OF ACTION
BREACH OF IMPLIED WARRANTY OF MERCHANTABILITY

82. Philips are merchants engaging in the sale of goods to Plaintiff and Members of the general public.

83. There was a direct sale of goods from Philips to Plaintiff, creating privity between Plaintiff and Defendants.

84. At all times mentioned herein, Philips manufactured or supplied the recalled machines, including the Philips DreamStation CPAP device used by Plaintiff, and prior to the time the Recalled machines, including the Philips DreamStation CPAP device used by Plaintiff and purchased by Plaintiff, Philips impliedly warranted to her that the Recalled machines, including the Philips DreamStation CPAP device used by Plaintiff was of merchantable quality, fit for its ordinary use, and conformed to the promises and affirmations of fact and omissions made on the Recalled machines, including the Philips DreamStation CPAP device used by Plaintiff's labels

and packaging, including that the Recalled machines, including the Philips DreamStation CPAP device used by Plaintiff was safe and appropriate for human use. Plaintiff relied on Philips' promises and affirmations of fact and omissions when he purchased and used the Recalled machines, including the Philips DreamStation CPAP device used by Plaintiff.

85. Contrary to these representations and warranties, the Recalled machines, including the Philips DreamStation CPAP device used by Plaintiff was not fit for its ordinary use and did not conform to Philips' affirmations of fact and promises and omissions because use of the Recalled machines, including the Philips DreamStation CPAP device used by Plaintiff is accompanied by the risk of adverse health effects, which does not conform to the labels and packaging of these devices.

86. Philips breached its implied warranties by selling a Recalled machines, including the Philips DreamStation CPAP device used by Plaintiff that failed to conform to the promises or affirmations of fact made on the packaging or label, as use of each Recalled machines, including the Philips DreamStation CPAP device used by Plaintiff was accompanied by the risk of developing adverse health effects that do not conform to the packaging or label.

87. Philips was on notice of this breach, as it was made aware of the adverse health effects accompanying use of the Recalled machines, including the Philips DreamStation CPAP device used by Plaintiff through user reports submitted to Philips and through lab testing.

88. Privity exists because Philips impliedly warranted to Plaintiff through the warranting, packaging, advertising, marketing, and labeling that the Recalled machines, including the Philips DreamStation CPAP device used by Plaintiff were natural, and suitable for use to treat health conditions, and made no mention of the attendant health risks associated with use of the Recalled machines, including the Philips DreamStation CPAP device used by Plaintiff.

89. As a direct and proximate result of the recalled machines, including the Philips DreamStation CPAP device's aforementioned defects as described herein, the Plaintiff has experienced significant mental and physical pain and suffering, has sustained permanent injury, has undergone medical treatment and will definitely undergo further medical treatment and procedures, has suffered financial or economic loss, including, but not limited to, obligations for medical services and expenses, and/or lost income, and other damages.

WHEREFORE, Plaintiff demands judgment against Defendants, and each of them, individually, jointly, severally and in the alternative, and requests compensatory damages, punitive damages, together with interest, costs of suit, attorneys' fees, and such further relief as the Court deems equitable and just.

SEVENTH CAUSE OF ACTION
FRAUDULENT MISREPRESENTATION

90. Philips failed to advise Plaintiff that the Recalled machines, including the Philips DreamStation CPAP device used by Plaintiff posed serious health risks to their users and Philips falsely represented to Plaintiff that the Recalled machines, including the Philips DreamStation CPAP device used by Plaintiff was safe for human use.

91. Philips intentionally, knowingly, and recklessly made these misrepresentations and omissions to induce Plaintiff and other members of the general public to purchase the Recalled machines, including the Philips DreamStation CPAP device used by Plaintiff.

92. Philips knew that its representations and omissions about the Recalled machines, including the Philips DreamStation CPAP device used by Plaintiff were false in that the Recalled machines, including the Philips DreamStation CPAP device used by Plaintiff contained PE-PUR Foam and thus were at risk of causing adverse health effects to users of the Recalled machines,

including the Philips DreamStation CPAP device used by Plaintiff, which does not conform to the products' labels, packaging, advertising, and statements. Philips knowingly allowed its packaging, labels, advertisements, promotional materials, and websites to intentionally mislead consumers, such as Plaintiff.

93. Plaintiff did in fact rely on these omissions and misrepresentations and purchased and used the Recalled machines, including the Philips DreamStation CPAP device used by Plaintiff to her detriment. Given the deceptive manner in which Philips advertised, represented, and otherwise promoted the Recalled machines, including the Philips DreamStation CPAP device used by Plaintiff, Plaintiff's reliance on Philips' omissions and misrepresentations was justifiable.

94. As a direct and proximate result of the recalled machines, including the Philips DreamStation CPAP device's aforementioned defects as described herein, the Plaintiff has experienced significant mental and physical pain and suffering, has sustained permanent injury, has undergone medical treatment and will definitely undergo further medical treatment and procedures, has suffered financial or economic loss, including, but not limited to, obligations for medical services and expenses, and/or lost income, and other damages.

WHEREFORE, Plaintiff demands judgment against Defendants, and each of them, individually, jointly, severally and in the alternative, and requests compensatory damages, punitive damages, together with interest, costs of suit, attorneys' fees, and such further relief as the Court deems equitable and just.

EIGHTH CAUSE OF ACTION
FRAUD

95. Philips concealed from and failed to disclose to Plaintiff that use of Recalled machines, including the Philips DreamStation CPAP device used by Plaintiff is accompanied by a risk of adverse health effects, which does not conform to the products' labels, packaging, advertising, and statements.

96. Philips was under a duty to disclose to Plaintiff the true quality, characteristics, ingredients and suitability of the Recalled machines, including the Philips DreamStation CPAP device used by Plaintiff because: (a) Philips was in a superior position to know the true state of facts about its products; (b) Philips was in a superior position to know the risks associated with the use of, characteristics of, and suitability of the Recalled machines, including the Philips DreamStation CPAP device used by Plaintiff for use by individuals; and (c) Philips knew that Plaintiff could not reasonably have been expected to learn or discover prior to purchasing the Recalled machines, including the Philips DreamStation CPAP device used by Plaintiff that there were misrepresentations and omissions by Philips in the packaging, labels, advertising, and websites regarding the health risks associated with use of these devices.

97. The facts concealed or not disclosed by Philips to Plaintiff were material in that a reasonable consumer would have considered them important when deciding whether to purchase the Recalled machines, including the Philips DreamStation CPAP device used by Plaintiff.

98. Plaintiff justifiably relied on Philips' omissions to his detriment. The detriment is evident from the true quality, characteristics, and risk associated with the use of the Recalled machines, including the Philips DreamStation CPAP device used by Plaintiff, which is inferior when compared to how the Recalled machines, including the Philips DreamStation CPAP device used by Plaintiff are advertised and represented by Philips.

99. As a direct and proximate result of the recalled machines, including the Philips DreamStation CPAP device's aforementioned defects as described herein, the Plaintiff has experienced significant mental and physical pain and suffering, has sustained permanent injury, has undergone medical treatment and will definitely undergo further medical treatment and procedures, has suffered financial or economic loss, including, but not limited to, obligations for medical services and expenses, and/or lost income, and other damages.

WHEREFORE, Plaintiff demands judgment against Defendants, and each of them, individually, jointly, severally and in the alternative, and requests compensatory damages, punitive damages, together with interest, costs of suit, attorneys' fees, and such further relief as the Court deems equitable and just.

NINTH CAUSE OF ACTION
NEGLIGENT MISREPRESENTATION

100. Philips had a duty to Plaintiff to exercise reasonable and ordinary care in the developing, testing, manufacture, marketing, distribution, and sale of the Recalled machines, including the Philips DreamStation CPAP device used by Plaintiff.

101. Philips breached its duty to Plaintiff and the Class by developing, testing, manufacturing, advertising, marketing, distributing, and selling products to Plaintiff and the Class that did not have the qualities, characteristics, and suitability for use as advertised by Philips and by failing to promptly remove the Recalled machines, including the Philips DreamStation CPAP device used by Plaintiff from the marketplace or to take other appropriate remedial action upon becoming aware of the health risks of the Recalled machines, including the Philips DreamStation CPAP device used by Plaintiff.

102. Philips knew or should have known that the qualities and characteristics of the Recalled machines, including the Philips DreamStation CPAP device used by Plaintiff were not as advertised or suitable for their intended use and were otherwise not as warranted and represented by Philips. Specifically, Philips knew or should have known that: (a) the use of the Recalled machines, including the Philips DreamStation CPAP device used by Plaintiff was accompanied by risk of adverse health effects that do not conform to the packaging and labeling; (b) the Recalled machines, including the Philips DreamStation CPAP device used by Plaintiff were adulterated, or at risk of being adulterated, by the PE-PUR Foam; and (c) the Recalled machines, including the Philips DreamStation CPAP device used by Plaintiff were otherwise not as warranted and represented by Philips.

103. As a direct and proximate result of Defendants' negligence, the Plaintiff has experienced significant mental and physical pain and suffering, has sustained permanent injury, has undergone medical treatment and will definitely undergo further medical treatment and procedures, has suffered financial or economic loss, including, but not limited to, obligations for medical services and expenses, lost income, and other damages.

WHEREFORE, Plaintiff demands judgment against Defendants, and each of them, individually, jointly, severally and in the alternative, and requests compensatory damages, punitive damages, together with interest, costs of suit, attorneys' fees, and such further relief as the Court deems equitable and just.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff prays for judgment against the Defendants, and each of them, as follows.

For past and future general damages on each cause of action, according to proof;

1. For past and future pain and suffering, according to proof;
2. For past and future hospital, medical, nursing care, treatment and incidental expenses, according to proof;
3. For past and future loss of earnings and earning power, according to proof;
4. For past and future mental and emotional distress, according to proof;
5. For restitution, according to proof;
6. For punitive damages in an amount appropriate to punish and/or set an example of Defendants, or is in any other way appropriate.
7. For past and future costs of suit incurred herein, and attorney's fees as may be allowed by law; and

For such other and further relief as the Court may deem just and proper.

DEMAND FOR JURY TRIAL

Plaintiff demands a trial by jury for all issues so triable.

Date of signing: September 30th, 2021.

Raymond Yu
District of Maryland Bar No.: 20988
828 West 35th Street
Baltimore, MD 21211
(410) 467-5492
Email: rlyu@post.harvard.edu

Exhibit A

Philips Recall Notice

PHILIPS

To the patients who use Philips Sleep & Respiratory Care devices:

Philips Respironics recently announced a voluntary recall for certain products in our Sleep & Respiratory Care portfolio. You are receiving this letter because you, or the medical equipment company that you work with, has provided your information and indicated you may be the user of a product impacted by this recall.

To help you understand if you are the user of one of the impacted products, we have enclosed two (2) attached medical device recall notifications. Please review them to determine if the Philips Sleep & Respiratory Care product you use is on the list of products impacted by this recall. If you are a user of an impacted product, please follow the instructions in the notification relevant to your specific product. These instructions detail the actions that should be taken immediately, including the directions to register your device, so we can begin the process of repair and/or replacement.

To register, to learn more information about this recall, or to see pictures of the impacted devices, please visit www.philips.com/src-update. If you cannot visit the web site, please call 1-877-907-7508. We regret the inconvenience and concern that this brings. We are committed to holding ourselves to the highest standards of product quality and safety in an effort to do what is right for the patients who rely on our products.

We will work to resolve this issue and will provide you with transparent, ongoing communication as we work to replace your product.

Thank you for your continued trust.

Rodney Mell
Head of Quality
Philips Respironics - Sleep & Respiratory Care

URGENT: Medical Device Recall

Philips Respironics
CPAP and Bi-Level PAP Devices

Sound Abatement Foam
Susceptibility to Degradation and Volatile Organic Compound Emission

To the patients who use Philips Sleep & Respiratory Care devices:

Philips Respironics is voluntarily recalling the below devices due to two (2) issues related to the polyester-based polyurethane (PE-PUR) sound abatement foam used in Philips Continuous and Non-Continuous Ventilators: 1) PE-PUR foam may degrade into particles which may enter the device's the air pathway and be ingested or inhaled by the user, and 2) the PE-PUR foam may off-gas certain chemicals. The foam degradation may be exacerbated by use of unapproved cleaning methods, such as ozone (see FDA safety communication on use of Ozone cleaners), and off-gassing may occur during initial operation and may possibly continue throughout the device's useful life.

These issues can result in serious injury which can be life-threatening, cause permanent impairment, and/or require medical intervention to preclude permanent impairment. To date, Philips Respironics has received several complaints regarding the presence of black debris/particles within the airpath circuit (extending from the device outlet, humidifier, tubing, and mask). Philips also has received reports of headache, upper airway irritation, cough, chest pressure and sinus infection. The potential risks of particulate exposure include: Irritation (skin, eye, and respiratory tract), inflammatory response, headache, asthma, adverse effects to other organs (e.g. kidneys and liver) and toxic carcinogenic affects. The potential risks of chemical exposure due to off-gassing include: headache/dizziness, irritation (eyes, nose, respiratory tract, skin), hypersensitivity, nausea/vomiting, toxic and carcinogenic effects. There have been no reports of death as a result of these issues.

All Devices manufactured before 26 April 2021, All serial numbers	
Continuous Ventilator, Minimum Ventilatory Support, Facility Use	E30 (Emergency Use Authorization)
Continuous Ventilator, Non-life Supporting	DreamStation ASV
	DreamStation ST, AVAPS
	SystemOne ASV4
	C-Series ASV
	C-Series S/T and AVAPS
	OmniLab Advanced+
Noncontinuous Ventilator	SystemOne (Q-Series)
	DreamStation
	DreamStation Go
	Dorma 400
	Dorma 500
	REMstar SE Auto

Immediate Actions to be taken by You, the User:

1. Discontinue use of your device and work with your physician or Durable Medical Equipment (DME) provider to determine the most appropriate options for continued treatment. To continue use of your device due to lack of alternatives, consult with your physician to determine if the benefit of continuing therapy with your device outweighs the risks identified in this letter.

2. Register your device on the recall website www.philips.com/src-update
   a. The website provides you current information on the status of the recall and how to receive permanent corrective action to address the two (2) issues.
   b. The website also provides you instructions on how to locate your device Serial Number and will guide you through the registration process.
   c. Call 1-877-907-7508 if you cannot visit the website or do not have internet access.

Permanent Corrective Action to be Taken by the Company:
Philips is deploying a permanent corrective action to address the two (2) issues described in this Recall Notice. As part of the registration process above, you will be provided information on the next steps to implement the permanent solution.

Other Information:
If you need any further information or support concerning this issue, please contact the recall support hotline or visit the website:

1-877-907-7508
www.philips.com/src-update

Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA's MedWatch Adverse Event Reporting program either online, or by regular mail or fax.

This notice has been reported to the appropriate Regulatory Agencies.

Philips regrets any inconveniences caused by this problem.

Sincerely,

Rodney Mell
Head of Quality
Philips Respironics - Sleep & Respiratory Care

URGENT: Medical Device Recall

Philips Respironics
Trilogy 100, Trilogy 200, Garbin Plus, Aeris, LifeVent, BiPAP V30, and BiPAP A30/A40 Series Device Models

Sound Abatement Foam
Susceptibility to Degradation and Volatile Organic Compound Emission

To the patients who use Philips Sleep & Respiratory Care devices:

Philips Respironics is voluntarily recalling the below devices due to two (2) issues related to the polyester-based polyurethane (PE-PUR) sound abatement foam used in Philips Continuous and Non-Continuous Ventilators: 1) PE-PUR foam may degrade into particles which may enter the device's air pathway and be ingested or inhaled by the user, and 2) the PE-PUR foam may off-gas certain chemicals. The foam degradation may be exacerbated by use of unapproved cleaning methods, such as ozone (see FDA safety communication on use of Ozone cleaners), and off-gassing may occur during operation.

These issues can result in serious injury which can be life-threatening, cause permanent impairment, and/or require medical intervention to preclude permanent impairment. To date, Philips Respironics has received several complaints regarding the presence of black debris/particles within the airpath circuit (extending from the device outlet, humidifier, tubing, and mask). Philips also has received reports of headache, upper airway irritation, cough, chest pressure and sinus infection. The potential risks of particulate exposure include: Irritation (skin, eye, and respiratory tract), inflammatory response, headache, asthma, adverse effects to other organs (e.g. kidneys and liver) and toxic carcinogenic affects. The potential risks of chemical exposure due to off-gassing include: headache/dizziness, irritation (eyes, nose, respiratory tract, skin), hypersensitivity, nausea/vomiting, toxic and carcinogenic effects. There have been no reports of death as a result of these issues.

All Devices manufactured before 26 April 2021, All serial numbers	
Continuous Ventilator	Trilogy 100
	Trilogy 200
	Garbin Plus, Aeris, LifeVent
Continuous Ventilator, Minimum Ventilatory Support, Facility Use	A-Series BiPAP Hybrid A30 (not marketed in US)
	A-Series BiPAP V30 Auto
Continuous Ventilator, Non-life Supporting	A-Series BiPAP A40
	A-Series BiPAP A30

Immediate Actions to be taken by You, the User:

1. Do not stop or alter your prescribed therapy until you have talked to your physician. Philips recognizes that alternate ventilator options for therapy may not exist or may be severely limited for patients who require a ventilator for life-sustaining therapy, or in cases where therapy disruption is unacceptable. In these situations, and at the discretion of the treating clinical team, the benefit of continued usage of these ventilator devices may outweigh the risks.

2. If your physician determines that you must continue using this device, **use an inline bacterial filter.** Consult your Instructions for Use for guidance on installation.

3. Register your device(s) on the recall website www.philips.com/src-update

   a. The website provides you current information on the status of the recall and how to receive permanent corrective action to address the two (2) issues.
   b. The website also provides you instructions on how to locate your device Serial Number and will guide you through the registration process.
   c. Call 1-877-907-7508 if you cannot visit the website or do not have internet access.

Permanent Corrective Action to be Taken by the Company:
Philips is deploying a permanent corrective action to address the two (2) issues described in this Recall Notice. As part of the registration process above, you will be provided information on the next steps to implement the permanent solution.

Other Information:
If you need any further information or support concerning this recall/issue, please contact the recall support hotline or visit the website:

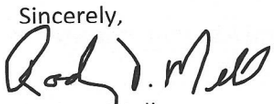
1-877-907-7508
www.philips.com/src-update

Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail or fax.

This notice has been reported to the appropriate Regulatory Agencies.

Philips regrets any inconveniences caused by this problem.

Sincerely,



Rodney Mell
Head of Quality
Philips Respironics - Sleep & Respiratory Care